April 17, 2025

BenQ Materials Corporation
℅ Jennifer Ting
RA Manager
Jens Medical Consulting Ltd.
3F, No 364, Jixian Rd, Luzhou Distr.
New Taipei City, 24747
Taiwan

Re: K242056
Trade/Device Name: miacare (miafilcon A) DELiGHT Contact Lens with EautraSil Plus/ miacare (miafilcon A) CONFiDENCE Color Contact Lens with EautraSil Plus/ miacare (miafilcon B) DELiGHT 1-Day Contact Lens with EautraSil Plus/ miacare (miafilcon B) CONFiDENCE 1-Day Color Contact Lens with EautraSil Plus
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: March 8, 2025
Received: March 14, 2025

Dear Jennifer Ting:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic.

See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

J Angelo Green -S

J. Angelo Green, Ph.D.
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1 : Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242056

Device Name
miacare (miafilcon A) DELiGHT Contact Lens with EautraSil Plus/ miacare (miafilcon A) CONFiDENCE Color Contact Lens with EautraSil Plus/ miacare (miafilcon B) DELiGHT 1-Day Contact Lens with EautraSil Plus/ miacare (miafilcon B) CONFiDENCE 1-Day Color Contact Lens with EautraSil Plus

Indications for Use *(Describe)*
miacare (miafilcon A) DELiGHT Contact Lens with EautraSil Plus is indicated as daily wear soft contact lens for correcting refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have refractive astigmatism of 1.00D or less, as long as the astigmatism does not impact visual acuity.
Eye care professional may prescribe the lens for single-use disposable wear, or for daily wear with frequent replacement. When prescribed for frequent replacement, the lens may be disinfected using a chemical disinfection system only.

miacare (miafilcon A) CONFiDENCE Color Contact Lens with EautraSil Plus is indicated as daily wear soft contact lens for correcting refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have refractive astigmatism of 1.00D or less, as long as the astigmatism does not impact visual acuity.
The color lens may enhance or alter the apparent color of the eye.
Eye care professional may prescribe the lens for single-use disposable wear, or for daily wear with frequent replacement. When prescribed for frequent replacement, the lens may be disinfected using a chemical disinfection system only.

miacare (miafilcon B) DELiGHT 1-Day Contact Lens with EautraSil Plus are designed for daily wear as single-use soft contact lenses for correcting refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have refractive astigmatism of 1.00D or less, as long as the astigmatism does not impact visual acuity.
Eye care practitioners may prescribe the lens for daily wear (disposable use) single use. The lenses are to be discarded upon removal. Therefore, no cleaning or disinfecting is required.

miacare (miafilcon B) CONFiDENCE 1-Day Color Contact Lens with EautraSil Plus are designed for daily wear as single-use soft contact lenses for correcting refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have refractive astigmatism of 1.00D or less, as long as the astigmatism does not impact visual acuity.
The lenses may enhance or alter the apparent color of the eye.
Eye care practitioners may prescribe the lens for daily wear (disposable use) single use. The lenses are to be discarded upon removal. Therefore, no cleaning or disinfecting is required.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY _ K242056

Preparation Date: April 14, 2025

5.1 Establishment Information:

Name	BenQ Materials Corporation
Address	29 Jianguo E. Road, Gueishan, 33341, Taoyuan, Taiwan, R.O.C.
Phone No.	886-3-3748800
Fax No.	886-3-3748888

5.2 US Agent:

Name	David Lennarz Registrar Corp.
Address	144 Research Drive Hampton, VA 23666 USA
Phone No	(734) 757 2240177
E-mail	David.Lennarz@ Registrarcorp.Com

5.3 Device Identification:

Proprietary Name	miacare (miafilcon A) DELiGHT Contact Lens with EautraSil Plus miacare (miafilcon A) CONFiDENCE Color Contact Lens with EautraSil Plus miacare (miafilcon B) DELiGHT 1-Day Contact Lens with EautraSil Plus miacare (miafilcon B) CONFiDENCE 1-Day Color Contact Lens with EautraSil Plus
Common Name	Soft (hydrophilic) Contact Lenses
Classification Name	Lenses, Soft Contact, Daily Wear (Disposable), (21 CFR 886.5925, Product Code LPL, MVN)
Classification	II

5.4 Legally Marketed Equivalent Device:

Predicate Device Name	OxyPure Color Silicone Hydrogel Soft Contact Lenses/ K171447 Si-Hy (olifilcon B) color silicone hydrogel soft contact lens/ K180322
Manufacturer	Visco Vision Inc.
Product Code	LPL, MVN

5.5 Device Description

miacare (miafilcon A) DELiGHT Contact Lens with EautraSil Plus and Miacare (miafilcon A) CONFiDENCE Color Contact Lens with EautraSil Plus

- They are daily wear soft contact lens for frequent replacement
- They are in a spherical lens design with UV blocker.
- They are available in hemispherical shell.
- The lens material is a silicon combination hydrogel. It is a copolymer of 1-vinyl-2-pyrrolidinone (NVP) and Siloxane macromer.
- The water content is 46%.
- A benzotriazole UV absorbing monomer is used to block UV radiation. The transmittance characteristics are less than 5% (2.31%) in the UVB range of 280-315nm and less than 50% (12.05%) in the UVA range of 316-380nm.
- The miacare (miafilcon A) DELiGHT Contact Lens with EautraSil Plus" is a light blue tinted with "reactive Blue19" for handling visibility purpose.
- The Miacare (miafilcon A) CONFiDENCE Color Contact Lens with EautraSil Plus is a color lens that may enhance or alter the apparent color of the eye.
- The lens is supplied in a sterile state, packaged in a buffered saline solution.

miacare (miafilcon B) DELiGHT 1-Day Contact Lens with EautraSil Plus and **miacare (miafilcon B) CONFiDENCE 1-Day Color Contact Lens with EautraSil Plus**

- They are daily wear soft contact lens for daily disposable
- They are in a spherical lens desing with UV blocker.
- They are available in hemispherical shell.
- The lens material is a silicon combination hydrogel. It is a copolymer of 1-vinyl-2-pyrrolidinone (NVP) and Siloxane macromer.
- The water content is 48%.
- A benzotriazole UV absorbing monomer is used to block UV radiation. The transmittance characteristics are less than 5% (2.36%) in the UVB range of 280-315nm and less than 50% (13.43%) in the UVA range of 316-380nm.
- The miacare (miafilcon B) DELiGHT 1-day Contact Lens with EautraSil Plus" is a light blue tinted with "reactive Blue19" for handling visibility purpose.
- The Miacare (miafilcon B) CONFiDENCE 1-day Color Contact Lens with EautraSil Plus is a color lens that may enhance or alter the apparent color of the eye.
- The lens is supplied in a sterile state, packaged in a buffered saline solution.

5.6 Indication for Use:

miacare (miafilcon A) DELiGHT Contact Lens with EautraSil Plus is indicated as daily wear soft contact lens for correcting refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have refractive astigmatism of 1.00D or less, as long as the astigmatism does not impact visual acuity.

Eye care professional may prescribe the lens for single-use disposable wear, or for daily wear with frequent replacement. When prescribed for frequent replacement, the lens may be disinfected using a chemical disinfection system only.

miacare (miafilcon A) CONFiDENCE Color Contact Lens with EautraSil Plus is indicated as daily wear soft contact lens for correcting refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have refractive astigmatism of 1.00D or less, as long as the astigmatism does not impact visual acuity.

The color lens may enhance or alter the apparent color of the eye.

Eye care professional may prescribe the lens for single-use disposable wear, or for daily wear with frequent replacement. When prescribed for frequent replacement, the lens may be disinfected using a chemical disinfection system only.

miacare (miafilcon B) DELiGHT 1-Day Contact Lens with EautraSil Plus are designed for daily wear as single-use soft contact lenses for correcting refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have refractive astigmatism of 1.00D or less, as long as the astigmatism does not impact visual acuity.

Eye care practitioners may prescribe the lens for daily wear (disposable use) single use. The lenses are to be discarded upon removal. Therefore, no cleaning or disinfecting is required.

miacare (miafilcon B) CONFiDENCE 1-Day Color Contact Lens with EautraSil Plus are designed for daily wear as single-use soft contact lenses for correcting refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who have refractive astigmatism of 1.00D or less, as long as the astigmatism does not impact visual acuity.

The lenses may enhance or alter the apparent color of the eye.

Eye care practitioners may prescribe the lens for daily wear (disposable use) single use. The lenses are to be discarded upon removal. Therefore, no cleaning or disinfecting is required.

5.7 Technological characteristics

miacare (miafilcon A) DELiGHT Contact Lens with EautraSil Plus/
miacare (miafilcon A) CONFiDENCE Color Contact Lens with EautraSil Plus

The spherical lens design specification:

- Diameter 13.0 mm to 15.0 mm
- Center Thickness 0.08mm @ -3.00D (Varies with Power)
- Base Curve 8.0 mm to 9.2 mm
- Power -12.00D to +8.00D

The physical properties of the lenses are:

- Refractive index: 1.407 (hydrated)
- Light transmittance: > 94%
- Water content: 46% by weight in normal saline
- Oxygen permeability 155×10^{-11} $(cm^2/sec)(ml\ O_2/ml.mmHg)$ measured at 35℃ (intrinsic Dk-Colormetric method)

miacare (miafilcon B) DELiGHT 1-Day Contact Lens with EautraSil Plus/
miacare (miafilcon B) CONFiDENCE 1-Day Color Contact Lens with EautraSil Plus

The spherical lens design specification:

- Diameter 13.0 mm to 15.0 mm
- Center Thickness 0.08mm @ -3.00D (Varies with Power)
- Base Curve 8.0 mm to 9.2 mm
- Power -12.00D to +8.00D

The physical properties of the lenses are:

- Refractive index: 1.405 (hydrated)
- Light transmittance: > 94%
- Water content: 48% by weight in normal saline
- Oxygen permeability 121×10^{-11} $(cm^2/sec)(ml\ O_2/ml.mmHg)$ measured at 35℃ (intrinsic Dk-Colormetric method)

5.8 Comparison table:

The characteristic comparison to predicate device is summarized in the following table.

Similarities			
Item	**Device**	**Device**	**Predicate (K171447)**
Product Name	miacare (miafilcon A) DELiGHT Contact Lens with EautraSil Plus	miacare (miafilcon A) CONFiDENCE Color Contact Lens with EautraSil Plus	OxyPure Color Silicone Hydrogel Soft Contact Lenses
Manufacturer	BenQ Materials Corp.	BenQ Materials Corp.	Visco Vision Inc.
Intended Use	Myopia, Hyperopia	Myopia, Hyperopia	Myopia, Hyperopia
USAN Name	miafilcon A	miafilcon A	olifilcon A
Material	Silicone Hydrogel	Silicone Hydrogel	Silicone Hydrogel
Lens Design	Spherical	Spherical	Spherical
Classification	Class II	Class II	Class II
Type	Group 5C (Nonionic, Water < 50 wt%)	Group 5C (Nonionic, Water < 50 wt%)	Nonionic, Water < 50 wt%
Water Content	46 %	46 %	47 %
Oxygen Permeability (DK, 35℃)	155 (Fatt method)	155 (Fatt method)	150 (Fatt method)
Base Curve Range	8.0~9.2	8.0~9.2	8.0~9.2
Diameter (mm)	13.0~15.0	13.0~15.0	13.0~15.0
Center Thickness	0.08 mm at -3.00D (Varies with design and power)	0.08 mm at -3.00D (Varies with design and power)	0.08 mm at -3.00D (Varies with design and power)
Powers	-12.00D to +8.00D	-12.00D to +8.00D	-20.00D to +20.00D
Replacement Schedule	Daily wear or Daily Disposable (Single use)	Daily wear or Daily Disposable (Single use)	Daily wear or Daily Disposable (Single use)
Refractive Index	1.407	1.407	1.410 (hydrated)
Light Transmittance	94%	94%	94%
Method of Manufacture	Cast-Molded	Cast-Molded	Cast-Molded
Surface Treatment	No	No	NA
Sterilization	steam	Steam	steam
Packaging	Blister pack	Blister pack	Blister pack
Blue handling tint	Yes, reactive Blue19	No	No
color additive for print	No	- Iron Oxide - Titanium dioxide - [Phthalocyaninato(2-)] copper - Carbazole violet	- Iron oxide - Titanium dioxide - Phthalocyanine green - Carbazole violet

Similarities			
Item	**Device**	**Device**	**Predicate (K180322)**
Product Name	miacare (miafilcon B) DELiGHT 1-day Contact Lens with EautraSil Plus	miacare (miafilcon B) CONFiDENCE 1-day Color Contact Lens with EautraSil Plus	Si-Hy (olifilcon B) Color Silicone Hydrogel Soft Contact Lens
Manufacturer	BenQ Materials Corp.	BenQ Materials Corp.	Visco Vision Inc.
Intended Use	Myopia, Hyperopia	Myopia, Hyperopia	Myopia, Hyperopia, Astigmatism, Presbyopia
USAN Name	Miafilcon B	Miafilcon B	Olifilcon B
Material	Silicone Hydrogel	Silicone Hydrogel	Silicone Hydrogel
Lens Design	Spherical	Spherical	Spheric, toric or multifocal
Classification	Class II	Class II	The same
Type	Group 5C (Nonionic, Water < 50 wt%)	Group 5C (Nonionic, Water < 50 wt%)	Group 5C (Nonionic, Water < 50 wt %)
Water Content	48 %	48 %	47 %
Oxygen Permeability (DK, 35℃)	121 (Fatt method)	121 (Fatt method)	120 (Fatt method)
Base Curve Range	8.0~9.2	8.0~9.2	8.0~9.2
Diameter (mm)	13.0~15.0	13.0~15.0	13.5~15.0
Center Thickness	0.08 mm at -3.00D (Varies with design and power)	0.08 mm at -3.00D (Varies with design and power)	Varies with design and power (0.08 mm at -3.00D)
Powers	-12.00D to +8.00D	-12.00D to +8.00D	-20.00D to +20.00D in 0.25 steps
Replacement Schedule	Daily Disposable (Single use)	Daily Disposable (Single use)	Daily Disposable (Single use)
Refractive Index	1.405	1.405	1.410
Light Transmittance	94%	94%	94%
Method of Manufacture	Cast-Molded	Cast-Molded	The same
Surface Treatment	No	No	No
Sterilization	steam	Steam	The same
Packaging	Blister pack	Blister pack	The same
Blue handling tint	Yes, reactive Blue19	No	NA
Color additives for print	No	- Iron oxide - [Phthalocyaninato (2-)] copper - Titanium dioxide - Carbazole violet	- Iron oxide - [Phthalocyaninato (2-)] copper - Titanium dioxide - Phthalocyanine green - Carbazole violet

5.9 Nonclinical Tests Performed

5.9.1 Physiochemical studies were conducted according to ISO 18369 First edition 2006-08-15, Ophthalmic optics - Contact lenses (Ophthalmic). The physical, optical and chemical properties of the lens are within established specifications for the lenses.

5.9.2 The biocompatibility evaluation was conducted in accordance with the FDA 1994 Guidance: "Class II Daily Wear Contact Lenses- Premarket Notification [510(k)] Guidance Document."

For lens materials (both miafilcon A and miafilcon B), the tests included:

- Cytotoxicity (ISO 10993-5)
- Guinea Pig Maximization Skin Sensitization (ISO 10993-10)
- Acute Systemic Toxicity (ISO 10993-11)
- Acute ocular irritation (10993-10)
- 22 Day Contact Lens Wear Study in Rabbits (ISO 9394).

For primary packing components:

- Cytotoxicity (ISO 10993-5)
- Acute ocular irritation (ISO 10993-23)
- Acute Systemic Toxicity (ISO 10993-11)

For the primary packaging solution:

- Cytotoxicity (ISO 10993-5)
- Acute ocular irritation (ISO 10993-10)

The biocompatibility results are acceptable in ocular environment.

5.10 Clinical Studies

miacare (miafilcon A) DELiGHT Contact Lens with EautraSil Plus and Miacare (miafilcon A) CONFiDENCE Color Contact Lens with EautraSil Plus

The clinical performance result proves that the safety and effectiveness of the miacare (miafilcon A) CONFiDENCE Color Contact Lens with EautraSil Plus is non-inferior to the OxyPure Color Silicone Hydrogel Soft Contact Lenses marketed by Visco Vision Inc.

A multi-center, open, parallel, randomized controlled comparison study with 90 days follow-up was conducted in mainland China. One hundred and ninety-two (192) subjects from 3 hospitals were enrolled in the study with 96 subjects wore the test lenses (miacare (miafilcon A) CONFiDENCE Color Contact Lens with EautraSil Plus) and 96 subjects wore the control lenses (OxyPure Color soft hydrophilic contact lens (olifilcon A). Of the 192 subjects, 172 subjects completed all scheduled visits (85 subjects in the test group and 87 subjects in the control group). There were 174 females and 18 males in the study

(female/male = 9.67/1). The average age of the subjects was 30.22 years (30.41 years in the test group and 30.03 years in the control group).

Patient Accountability:

Stage	Investigational Device Arm Total	Control Arm Total	Total
Enrollment	96	96	192
Treatment	95	96	191
Primary Safety Endpoint Analysis	85	87	172
Primary Effectiveness Endpoint Analysis	85	87	172

The clinical study shows that no significant difference between the study device and control device in terms of safety and efficacy. Both groups shows that the CVA could reach equal or higher than 1.0 and the color lens will enhance or alter the apparent color of the eye.

No adverse reaction was reported for both test group and control group related to hazardous, sight-threatening condition for both the trial group and control group in terms of corneal ulcers, severe corneal abrasion > 2mm in diameter, iritis, other ocular infections or inflammations, corneal scarring, or permanent loss of vision.

No statistic significant difference between test lens and control lens with respect to safety data including adverse reaction data, slip lamp findings, symptoms/problems/complications, Keratometry (K) readings, refractive changes (absolute value) and visual acuity (VA) data, average wearing time (AWT), discontinuations and lens replacement.

miacare (miafilcon B) DELiGHT 1-Day Contact Lens with EautraSil Plus and **miacare (miafilcon B) CONFiDENCE 1-Day Color Contact Lens with EautraSil Plus**

The clinical performance result proves that the safety and effectiveness of the miacare (miafilcon B) CONFiDENCE Color Contact Lens with EautraSil Plus is non-inferior to the Si-Hy (olifilcon B) Color Silicone Hydrogel soft contact lens currently marketed by Visco Vision Inc.

A multi-center, open, parallel, randomized controlled comparison study with 90 days follow-up was completed in mainland China. One hundred and ninety-two (192) subjects from 3 hospitals were enrolled in the study with 96 subjects wore the test lenses (miacare (miafilcon B) CONFiDENCE Color Contact Lens with EautraSil Plus) and 96 subjects wore the control lenses (Si-Hy Color silicone hydrogel soft contact lens (olifilcon B). Of the 192 subjects enrolled, 192 subjects completed all scheduled visits (96 subjects in the test group and 96 subjects in the control group). There were 179 females and 13 males in the study (female/male = 13.77/1). The average age of the subjects was 29.745 years (29.68 years in the test group and 29.81 years in the control group).

Patient Accountability:

Stage	Investigational Device Arm Total	Control Arm Total	Total
Enrollment	96	96	192
Treatment	96	96	192
Primary Safety Endpoint Analysis	96	96	192
Primary Effectiveness Endpoint Analysis	96	96	192

The clinical study shows that no significant difference between the study device and control device in terms of safety and efficacy. Both groups shows that the CVA could reach equal or higher than 1.0 and the color lens will enhance or alter the apparent color of the eye.

No adverse reaction was reported for both test group and control group related to hazardous, sight-threatening condition was found for both the trial group and control group in terms of corneal ulcers, severe corneal abrasion > 2mm in diameter, iritis, other ocular infections or inflammations, corneal scarring, or permanent loss of vision.

No statistic significant difference between test lens and control lens with respect to safety data including adverse reaction data, slip lamp findings, symptoms/problems/complications, Keratometry (K) readings, refractive changes (absolute value) and visual acuity (VA) data, average wearing time (AWT), discontinuations and lens replacement.

5.11 Conclusion

Based on the non-clinical and clinical tests, it is concluded that the contact lenses, miacare (miafilcon A) DELiGHT Contact Lens with EautraSil Plus, miacare (miafilcon A) CONFiDENCE Color Contact Lens with EautraSil Plus, miacare (miafilcon B) DELiGHT 1-Day Contact Lens with EautraSil Plus, and miacare (miafilcon B) CONFiDENCE 1-Day Color Contact Lens with EautraSil Plus are substantially equivalent to the predicate devices. The lens material is not the same. However, it doesn’t raise any questions of safety and effectiveness. These devices are as safe, as effective and performs as well as the predicate devices.